Weak and Strong Interpretations of the Precautionary Principle in the Risk Management of Modern Biotechnology[1]

Marko Ahteensuu

Abstract

The so-called precautionary principle is presumed to provide guidance when our knowledge of the possible harmful consequences of an action alternative is uncertain. In the context of modern biotechnology risk governance, the precautionary principle has been a matter of heated debate, and it has become common to distinguish between the weak and strong interpretation of the principle. In this paper, the traditional weak-strong distinction, which has been assumed to clarify the ongoing discussion, is problematized. In particular, it is argued that the distinction is ambiguous, and thus that the distinction does not provide a useful tool for the rational discussion and evaluation of different readings of the precautionary principle, as is usually thought. Further to this, different interpretations of the principle are evaluated on theoretical and practical grounds.

Introduction

The precautionary principle (henceforth, the PP) is an important and widely accepted risk management instrument of modern biotechnology.[2] According to it, uncertainty concerning the potential harmful effects of an activity—e.g. the development and use of a technology or the market approval of a new product—should not be used as a reason to postpone measures to prevent potential damage. In a sense, the principle embodies the folk wisdom, 'better safe than sorry'.

The PP is mentioned in national environmental laws, and many governments have accepted the principle as a basis for policymaking. In Finland, for instance, the reformed *Genetic Engineering Act* (2004/847) mentions the PP in the first paragraph. An interesting example of the latter can be found in Austrian biotechnology policies. The Austrian standard of genetically modified organism (GMO) risk assessment goes

beyond the strict scientific understanding of risk, and it can thus be seen as precautionary in nature (Torgersen & Seifert 2000). At the European Union (EU) level, the *Directive 2001/18/EC* on the deliberate release and placing on the market of GMOs is based on the PP. In international environmental law, the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (CPB 2000), which regulates the transfer, handling and use of living modified organisms (LMOs), includes the PP as a key element.

Despite the influential role of the PP in the environmental law (and more generally in societal risk governance), the principle is formulated in various ways in official documents, and there is a debate over its precise meaning (see e.g. Adams 2002; Manson 2002; Parker 1998; Sandin 1999; Vander-Zwaag 2002). It has become common to distinguish between the weak and strong interpretation of the PP (henceforth, the traditional distinction) on the basis of different formulations in official documents (e.g. Conco 2003; Morris 2000; Parker 1998; Soule 2002). In general, the weak interpretation requires slighter precautionary measures than does the strong one. Moreover, the application of precautionary measures presupposes more evidence for the causal relationship between an action and the assumed damage.

In this paper, I will examine the traditional distinction. I defend the thesis that the distinction has been made using various criteria, and thus that the traditional distinction is ambiguous. Secondly, I shall evaluate some of the interpretations which follow from the use of different decisive criteria in the weak-strong distinction with theoretical and practical (e.g. moral) considerations. Specific formulations of the PP (and precautionary policy decisions and arguments) in modern biotechnology risk governance (and debate) are used as examples of the different interpretations of the principle. The approach of the study is philosophical, in particular conceptual and ethical analysis.

The traditional distinction between the strong and weak interpretation of the precautionary principle

The most well-known and influential formulation of the PP is probably the principle 15 of the *Rio Declaration on Environment and Development* (1992):

> In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Another noted formulation of the principle is found in the *Wingspread Statement on the Precautionary Principle* (1998):

> [I]t is necessary to implement the Precautionary Principle: When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.
>
> In this context the proponent of the activity, rather than the public, should bear the burden of proof.
>
> The process of applying the precautionary principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the range of alternatives, including no action.

It is obvious that these two formulations differ. For example, the former says only that uncertainty shall (should) not be used as a reason not to take cost-effective precautionary measures, while the latter states an obligation to take precautions with no reference to cost-effectiveness. Furthermore, the latter shifts the burden of proof from the public (regulators and non-governmental organizations [NGOs]) to industry (and the scientific community). Yet these two formulations are considered 'the standard examples' of the PP. Actually, the 'Rio formulation' is commonly thought to represent a paradigm example of the weak interpretation, while the 'Wingspread Statement' is the most frequently provided example of the strong form (Morris 2000; Soule 2002).

This traditional distinction between the strong and weak interpretation of the PP is common and made by several authors. In practice, it means that different formulations of the principle in official documents and various precautionary policy decisions are subsumed into two interpretations and that thereafter the strong and weak form are evaluated independently (e.g. Morris 2000; Soule 2002). The purpose is explicatory, that is, the distinction is presumed to provide a useful tool for the evaluation of different understandings of the PP.

Julian Morris, for instance, argues that 'it is worth distinguishing two broad classes' of interpretations of the PP. His definition of the strong interpretation says: 'take no action unless you are certain that it will do no harm'. According to the weak form, 'lack of full certainty is not a justification for preventing an action that might be harmful' (Morris 2000, 1). Edward Soule also sorts various formulations of the PP into the strong and weak interpretation. According to him, the weak form 'provides [regulators with] the authority to override other factors and make environmental risk the paramount and deciding concern'. This is, however, optional because 'the weak form does not mandate that regulators treat environmental risk this way'. On the other hand, the strong interpretation restricts 'regulators to consider environmental risk in isolation from possible benefits'. Moreover, taking precautions is not optional but mandatory. Soule states that '[t]he key feature that distinguishes this formulation from weak versions is the lack of reference to factors other than environmental risk' (Soule 2002, 18–19, 22, 24–25).

Problematizing the traditional distinction

Morris' and Soule's definitions of the traditional distinction clearly differ and also contain some problems. However, I am not eager to analyse these particular differences or problems, but rather to question the (usefulness of the) traditional distinction itself. Specifically, I try to show that the distinction is made on the basis of different (sometimes even several) criteria—instead of one and the same or generally agreed ones, as it is usually presumed—in order to illustrate the ambiguity of the distinction.

Status of scientific evidence

Sometimes it is thought that the distinctive criterion which distinguishes the strong interpretation from the weak interpretation is the status of scientific evidence (e.g. ECNH 2003, 11–13). Accordingly, the weak interpretation says that any implementation of precautionary measures presupposes scientific evidence for a hazard which has been identified in the preceding risk assessment (Morris 2000, 6–7; see also Foster, Vecchia

& Repacholi 2000).[3] Examples of this kind of weak interpretation can be easily found. In their *Communication on the Precautionary Principle*, the Commission of the European Communities states that

> [t]he implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty (CEC 2000, 17).

Furthermore, the *Cartagena Protocol on Biosafety* says that a denial of LMO import can be based upon lack of scientific knowledge or scientific consensus, but also that the '[r]isk assessment should be carried out in a scientifically sound and transparent manner (…) [and] on a case-by-case basis' (CPB 2000, Annex III).

On the other hand, according to the strong interpretation of the PP, scientific evidence of a hazard is not a necessary condition for the application of the principle. Precautions are justified if it is conceivable that the planned activity would cause a disaster. In fact, some formulations of the PP in the legal texts seem not to imply the requirement for scientific evidence. According to one international agreement on marine environmental protection, precautions can be taken 'even when there is no scientific evidence to prove a causal link between emission and effects' (*Declaration of the Third International Conference on the Protection of the North Sea* 1990, Preamble). In relation to modern biotechnology, appeals to ignorance concerning the consequences of an activity in order to prohibit that activity are sometimes found in the statements of (social) scientists, NGOs and laypersons. The strong interpretation of the PP can also be predicated to some national policies. For example, in official comments on herbicide-tolerant plants in 1994, the Austrian competent authority 'mentioned concerns not only about predictability but also about hypothetical outcomes' (Torgensen & Seifert 2000, 210). Neil A. Manson calls this kind of interpretation of the PP the catastrophe principle. It says that

> if we can identify an e[nvironmental]-activity and an e-effect such that the e-effect is catastrophic and it is merely possible that the e-activity causes the e-effect, then the imposition of the e-remedy is justified regardless of the probability that the e-activity causes the e-effect (Manson 2002, 270).

This kind of strong interpretation is open to criticism. According to it (or the catastrophe principle), an action should be prohibited (or it is justified to prohibit an action) if there is a mere possibility of severe damage. One problem results from the use of the term *possible*. Different states of affairs seem to be possible in the future, and this derives (at least partly) from our imperfect knowledge of nature's complex relationships. Some courses of events are probable on the basis of our current (scientific) knowledge—others are not. This is not problematic. However, possible events also include events (in the future) which cannot be excluded on the grounds of current knowledge. The world may end tomorrow, and it is a fact that we are not sure that it will not (although it may be highly improbable). Similarly, if the application of the PP would not presuppose any kind of 'scientific' evidence, the principle could be applied randomly on the basis of almost any imagined threat. This would, certainly, be fatal for the justifiability of the principle in societal decision-making. Moreover, the definition of the catastrophe principle is problematic in itself because it is also possible that the invoked precautionary measures result in a catastrophe (see Manson 1999). In these cases, the principle leads to contradictory instructions for action.

To sum up, this kind of strong interpretation is not plausible. More generally, it follows that the PP cannot be applied in the absence of any evidence. Although no conclusive scientific evidence of a hazard is available in the state of uncertainty, some kind of evidence is necessary (see e.g. Adams 2002; Resnik 2003).

Placing the burden of proof

The traditional distinction is often associated with placing the burden of proof (e.g. Wiener & Rogers 2002, 321; see also Hohmann 1994, 334). Accordingly, the strong interpretation of the PP says that the onus of proof should be reversed. Manson, for instance, states that

> [o]n stronger versions of it, PP is also a burden-adding principle; those desiring to Ø [a proposed technological/industrial activity] must show that Ø does not lead to Ω [a harmful environmental outcome]; if they cannot do so with a high degree of certainty, they should not be permitted to Ø (Manson 1999, 12).

Generally, this kind of strong interpretation is common, and some shift in the burden of proof follows from the very basic idea of the PP. Jenneth Parker points out that often

> the principle is viewed as a shifting of the burden of proof: instead of environmentalists having to demonstrate damage after the fact, the PP is viewed as shifting the onus onto the potential polluter to demonstrate that what they propose will not cause damage. In a survey of biologists, lawyers, and administrators it was found that 80% supported this interpretation of the PP (Parker 1998, 635).

It has been argued that a concrete example of the strong interpretation can be found in Austrian gene technology policies. Helge Torgensen and Franz Seifert claim that

> [w]hile administrators in other countries are satisfied if there is no evidence of risk, Austrian administrators demand more evidence of safety and consideration of all possible uncertainties, which are not tolerated (…). The Austrian objections to marketing applications depend less on demonstrating 'risk' than on reversing the burden of evidence (…) in a television interview (…) the Minister in charge even demanded exclusion of any risk (Torgensen & Seifert 2000, 212).

On the other hand, the weak interpretation embodies the idea that decision-makers can more easily interfere in actions of industry and the scientific community. In this respect, the PP can be seen as a policy instrument which is used to justify restrictions when policymakers have no scientific proof that the planned actions would cause harm. Following Manson's account,

> [o]n weaker versions of it, PP is a burden-removing principle; those who would regulate Ø no longer need meet the normal scientific standards for establishing that Ø causes Ω; reasonable suspicions that Ø causes Ω are enough to justify regulating Ø (Manson 1999, 12).

A concrete example of this can be found in the *Cartagena Protocol on Biosafety*:

> [l]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living

> modified organism (…) shall not prevent that Party from taking a decision, as appropriate with regard to the import of the living modified organism in question (…) in order to avoid or minimize such potential adverse effects (CPB 2000, Article 10).

Remarks should be made on this distinction. Firstly, these two interpretations are not mutually exclusive. This is due to the fact that it is possible to implement a regulation whereby the proponents (i.e. producers) of a (new) technology or product are required to conduct more safety experiments than they would do in the traditional risk assessment of similar kinds of technologies or products, and whereby the threshold for regulatory interventions in companies or the scientific community is lowered.

Secondly, the requirement for the reversal of the burden of proof is closely linked to the methods of scientific inquiry, that is, to the statistical analysis in quantitative studies. Specifically, this concerns the choice between minimizing false positives (type-I error) and false negatives (type-II error). In the context of scientific risk analysis, type-I error refers to a situation where we conclude wrongly that a technology is unsafe, whereas type-II error refers to a situation where we conclude wrongly that no severe damage will result from using a technology. Minimizing type-I errors reduces the chance of accepting false identifications of risks as the basis of decision-making. Accordingly, there is a greater burden of proof on the individuals or collectives who postulate some, rather than no, severe consequences. On the other hand, minimizing type-II errors would reduce neglected real risks with harmful consequences in environmental and health decision-making. This would place the burden of proof on risk imposers rather than on risk victims and regulators.[4]

Thirdly, there is a theoretical problem in the requirement for the total reversal of the burden of proof. Namely, it includes a commitment to the following kind of negative existential claim: there exists no possible environmental state of affairs which arises out of the particular activity under scrutiny, and which has the properties of being harmful and highly undesirable. It is, of course, impossible to demonstrate that an action has no harmful consequences. The best we can do is to show that an action has not the harmful consequences which we can identify in risk assessment, particularly in hazard identification.[5] However, it is not possible to test

risks that we do not know about. We do not know the exact scope of our ignorance; and, the PP is not going to help us in this matter. An action may always have direct or indirect consequences which cannot be specified on the basis of the current state of knowledge, and consequently it is impossible to subject these possibilities to scientific risk analysis. In sum, when the requirement for the total reversal of the burden of proof is used to distinguish between the weak and strong interpretation of the PP, it follows that the latter (i.e. the strong form) is not plausible.

Normative status of precautionary measures

In many cases, the traditional distinction is made by referring to the normative status of precautionary measures (e.g. Conco 2003, 641; see also Cameron & Wade-Gery 1995, 100, 135). For example, Olivier Godard writes that

> il peut être justifié (version faible) ou il est impératif (version forte), de limiter, d'encadrer ou d'empêcher certaines actions potentiellement dangereuses sans attendre que ce danger soit scientifiquement établi de façon certaine (Godard 1997, 25).[6]

The strong form can be identified in some environmental policy documents, for instance in the *World Charter for Nature* (1982) and in the *Wingspread Statement* (1998). As noted above, a paradigm example of the weak interpretation is often held to be the principle 15 of the *Rio Declaration on Environment and Development* (1992) (Conco 2003, 640–641). However, it should be noted that the 'Rio formulation' only states that uncertainty concerning a threat 'shall not be used as a reason to postpone' precautionary measures, not that the uncertainty in itself gives a justification to take precautions. Consequently, the formulation has to be seen as a slighter version of the weak interpretation (see Cameron & Wade-Gery 1995; Wiener & Rogers 2002).

Interestingly, the weak interpretation seems to be problematic when applied at international level. In certain cases, it may be difficult (or even impossible) to prove that precaution is not applied as 'a disguised restriction

on trade' (Matthee & Vermersch 2000, 69). Because taking precautionary measures is justified (and thus optional) in the absence of evidence which counts as scientific in the strict sense, the boundary between environmental protection and illicit trade barriers becomes blurred. In other words, the (contextual) threshold(s) for well-founded precautions is hard to define accurately, and it can always be intentionally disputed in order to promote interests unrelated to the environmental protection.

Status of cost-benefit analysis

Sometimes the strong and weak interpretation of the PP has been distinguished by referring to the status of cost-benefit analysis (e.g. Myhr & Traavik 2003, 229; see also Soule 2002, 18, 22). The strong interpretation, then, implies that an action should be prohibited if it is credible that it may cause an unacceptable damage. The prohibition is categorical: consequences, i.e. possible costs and benefits of the prescribed precautionary measure, are not taken into consideration. André Nollkaemper describes this kind of interpretation of the PP as follows,

> [a] strictly absolutist construction of the principle would require the use of cost-oblivious standards that have the prevention of risks as their sole and non-compromised objective and aim to protect the environment against risks regardless of what a cost-benefit analysis may suggest (Nollkaemper 1996, 87).

It has been argued (most often by NGOs) that the use of modern biotechnology in general or some of its applications in particular should be prohibited because of (irreducible) uncertainties concerning its potential harmful effects in spite of its known and possible benefits. Moreover, certain formulations of the PP in the law texts seem to imply the use of cost-oblivious standards (see e.g. Nollkaemper 1996; Soule 2002).

On the other hand, the weak interpretation embodies the idea 'be cautious, but act'. Instead of straightforward bans and moratoria on technologies and products, precautionary measures can, for example, consist of extended risk assessment or stricter monitoring procedures. Ultimately, the idea is that the chosen precautionary measures should be cost-effective.

The possible consequences, i.e. the costs and benefits of different measures and the option of having no measures at all, should be considered.[7]

Concrete examples of this kind of weak interpretation can easily be found (e.g. *Rio Declaration on Environment and Development* 1992). According to the Commission of the European Communities,

> [t]he measures adopted presuppose examination of the benefits and costs of action and lack of action. This examination should include an economic cost/benefit analysis when this is appropriate and feasible (CEC 2000, 20).

When the status of cost-benefit analysis is used to distinguish between the weak and strong interpretation of the PP, the latter is open to criticism. Firstly, implementing the strong interpretation can result in a loss of considerable benefits because of the restricted technologies. When benefits are large and the risk of serious damage (to the environment and/or human health) is highly improbable, the prohibition of the activity in question would be (extremely) impractical. Furthermore, in these cases, the choice of prohibitions as precautionary measures can also be seen as immoral, if we consider morality based on consequentialistic ethics. Secondly, this interpretation appears not to include the idea that precautionary measures can vary greatly, as is commonly thought (e.g. VanderZwaag 2002). Finally, even if the PP were cost-oblivious, the fact that the PP is above all a legal *principle* would limit this absolutism in practice. The PP offers only one reason to act on environmental matters. Other principles should also be taken into consideration in decision-making, and these principles usually make it possible to balance risks and potential benefits.

In sum, this kind of strong interpretation faces a number of problems. Yet there are certain grounds for the interpretation. For example, it could be argued that it would be immoral to weigh probable losses of human lives against (possible) economic benefits, and thus that the justifiability of the interpretation is ultimately dependent upon the definition of unacceptable threat. In the case of some threats, the weighing up of possible benefits and costs is well-founded, while in other cases it is definitely not. The plausibility of this view is still contested, however.

Discussion

So far, the thesis that the traditional distinction is ambiguous has been defended. In particular, I have identified four criteria which have often been used to distinguish between the weak and strong interpretation of the PP. I have further argued that some of the interpretations which follow from the use of different decisive criteria face theoretical and/or practical problems, and thus questioned the plausibility or justification of these interpretations.

My first point, the argument from ambiguity, requires further elaboration. To begin with, it should be emphasized that I do not claim that the traditional distinction has not been made otherwise, i.e. by using other decisive criteria. For my purposes, it would even be enough to show that the distinction has been made using two criteria instead of the identified four.

Perhaps more importantly, the significance and implications of my observation may not be immediately obvious. In order to neutralise possible objections, and to make my argument more substantial, let us consider the consequences of the use of different criteria under the name of the traditional distinction. In particular, the ambiguity of the traditional distinction results in:

(1) *A normative problem*. By this I mean that the ambiguity concerning the strong and weak interpretation gives rise to difficulties in evaluating the rationality and moral acceptability of different understandings of the PP.

(2) *A practical problem*, i.e. difficulties in the interpretation and application of laws which invoke the principle.

(3) *An argumentative problem*. When commitments to the weak and/or strong interpretation are made without identifying what is meant by these interpretations, the argumentation cannot be sound.

(4) *Misconceptions*. The implicit use of the identified criteria under the name of strong and weak interpretation has led to misconceptions.

Somebody might try to object, and argue that no problems arise if the decisive criterion used is stated explicitly. However, this does not dissolve the

ambiguity problem. Consider the argumentative problem as an example. The argumentation based upon the explicated weak and/or strong interpretation of the PP may still be unsound: premises could be unconvincing (claims of facts might be false and/or values disputed), and the inference from premises to conclusion could be fallacious. But even if we sidestep the possibility of defective argumentation, it seems to be a fact that (1) there are several criteria (not only a single one) and that (2) there is no agreement upon which one(s) is the right one. Terms such as Weak1/Strong1, Weak2/Strong2 and so on could be introduced, but in the end it would not be worthwhile. It would be easier to state merely the criterion used without any reference to the weakness or strength of the interpretations which follow. Furthermore, the use of these terms (e.g. Weak1, Weak2) is also problematic, because two (or even more) criteria are frequently applied at the same time. Soule (2002, 25–26), for example, seems to use the status of cost-benefit analysis and the normative status of precautionary measures as the decisive features. In short, the ambiguity disappears hand in hand with the abandonment of the traditional distinction. When the distinguishing criterion used is stated explicitly, the mention of the traditional distinction becomes redundant.

Another kind of attempt to criticise my argument would be to claim that some authors speak about the strong and weak interpretation as a continuum, not as sharply distinguished groups. Indeed, it is true that some authors refer to a continuum instead of two classes, but this has no relevant implications for the argument from ambiguity. In order to establish the argument, the interpretations can be regarded as distinguishable groups or as a continuum. In the end, there are at least four criteria or continua, and no agreement upon which is the right one.

Furthermore, it might be argued that the traditional distinction should not be abandoned because it has some practical or heuristic value regardless of its shortcomings. The argument could be that, even if we cannot agree upon the exact meaning of the traditional distinction, we can still point out certain clear cases (i.e. commonly accepted examples of the two interpretations), and thus the distinction can offer a useful basis for the discussion of different formulations of the principle. Well, as I have tried to show above, it does not. It is more useful to evaluate different formulations of

the PP one by one, or on the basis of explicitly stated criteria as I have done in this paper, than in the light of a flawed distinction.

Two final remarks: I have introduced one reason not to use the traditional distinction. This does not, of course, exclude the possibility of other arguments against the distinction.[8] Second, it seems plausible, if not self-evident, that my considerations in this paper apply not only to the risk governance of modern biotechnology but also more generally to the use of the PP in environmental and health risk governance.[9]

Notes

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2 The principle is sometimes also referred to as *precaution, the principle of precaution and the precautionary approach*. In this paper, I use the term PP as an umbrella term for these expressions.

3 Risk assessment is a part of scientific risk analysis, which also includes risk management and risk communication.

4 The choice between minimizing type-I errors or type-II errors is not an easy one—the choices are mutually exclusive (for further discussion, see e.g. Shrader-Frechette 1991).

5 Risk assessment commonly consists of hazard identification, dose-response assessment, exposure assessment and risk characterization.

6 '[I]t may be justifiable (weak version) or [it is] mandatory (strong version) to limit, regulate, or prevent potentially dangerous actions before scientific proof is established' (I follow Philippe H. Martin's translation).

7 Here, I do not mean to restrict the assessment of possible benefits and costs only to economic considerations.

8 Actually, there are (at least two) other reasons for abandoning the traditional distinction. The arguments in a nutshell: first, the traditional distinction is not exhaustive, i.e. it does not cover the variety of understandings of the PP; second, the traditional distinction is semantically misleading.

9 The proposed arguments appear not to be specific for the debate on modern biotechnology. Of course, this does not exclude the possibility that well-grounded arguments which apply only in the context of modern biotechnology could be presented.

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